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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SMITH, TERRIL

ART UNIT PAPER NUMBER

3762

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,069

Applicant(s)

FRERICKS ET AL.

Examiner

Terri L. Smith

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 16-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/03, 4/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 – 15 and 28 – 29, drawn to a stimulation electrode, classified in class 607, subclass 122.
 - II. Claims 16 – 27, drawn to a method for producing a stimulation electrode, classified in class 29, subclass 729.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I (product) and Group II (process) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process not involving the method PVD, but rather by the method of molding. Additionally, in the instant case the product as claimed can be made by another and materially different process not involving depositing the metallic layer or an oxidation process, but rather growing the layer or spraying/depositing the oxide. Further, in the instant case the product as claimed can be made by another and materially different process not involving oxidizing the titanium electrode base by thermal oxidation, but rather by sputtering. Also in the instant case, the product as claimed can be made by another and materially different process not involving oxidizing the tantalum electrode base by thermal oxidation, but rather by vacuum technology. And in the instant case the product as claimed can be made by another and materially different

Art Unit: 3762

process not involving oxidizing the titanium nitride electrically conducting layer by thermal oxidation, but rather by a laser.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with William W. Schwarze on Monday, April 18, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1 – 15 and 28 – 29. Affirmation of this election must be made by applicant in replying to this Office Action. Claims 16 – 27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The disclosure is objected to because of the following informalities: On page 2, the phrase "... set for the at the outset in ..." (line 5) is unclear. It is unclear what is being disclosed.

Appropriate correction is required.

Claim Objections

7. Claims 1 and 9 are objected to because of the following informalities: In claim 1, a period punctuation mark is after the word “niobium” (line 4). It is suggested to change it to a comma.

In claim 9, a space should be placed between the right parenthesis of the parenthetical “(5d, 5e, 5f, 5g)” and the word “on” (line 2).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 28 – 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 28, “in a form” is vague since the scope and limitation of “in a form” is vague and relative. It is suggested to use “wherein the electrode is implantable.”

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3762

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1 – 5, and 28 - 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolz, U.S. Patent 5,609,611.

Regarding Claim 1, Bolz discloses an electrically conducting electrode base member (Fig. 4; column 8, lines 18 – 19) partially covered with an electrically insulating ceramic layer, wherein the ceramic layer is formed of an oxide and/or an oxynitride of at least one metal selected from the group consisting of titanium, niobium, tantalum, zirconium, aluminum, and silicon (column 10, lines 51 – 52), and wherein the electrode base member is further at least partially coated with an electrically conducting layer comprising at least one material selected from the group consisting of titanium nitride, niobium nitride, tantalum nitride, zirconium nitride, aluminum nitride, silicon nitride, vanadium nitride, iridium oxide, and an alloy of platinum and iridium, wherein the iridium portion of the alloy is ≥ 21 wt. % and the platinum portion of the alloy is \geq about 100 ppm (column 8, lines 59 – 60).

Regarding Claim 2, Bolz discloses an electrode base member is formed of at least one metal selected from the group consisting of titanium, tantalum, gold, carbon, platinum, iridium, platinum-iridium alloys, alloys based on cobalt and/or nickel, and stainless steel (column 6, line 59).

Regarding Claim 3, Bolz discloses a ceramic layer is arranged on an electrically conducting layer (column 8, lines 18 – 22).

Art Unit: 3762

Regarding Claim 4, Bolz discloses a ceramic layer is arranged adjacent an electrically conducting layer on an electrode base member (column 8, lines 18 – 22).

Regarding Claim 5, Bolz discloses an electrically conducting layer is formed of titanium nitride (column 8, lines 59 – 60).

Regarding Claim 28, Bolz inherently discloses a form of a human implant (Fig. 4; column 1, lines 8 – 9).

Regarding Claim 29, Bolz discloses a cardiac pacemaker electrode or a neuro-stimulation electrode (column 1, lines 7 – 8; column 9, line 9).

12. Claims 1 – 10, 14 – 15, and 28 - 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bussard, U.S. Patent 4,440,178.

Regarding Claim 1, Bussard discloses an electrically conducting electrode base member (Fig. 1; column 4, lines 4 – 6) partially covered with an electrically insulating ceramic layer, wherein the ceramic layer is formed of an oxide and/or an oxynitride of at least one metal selected from the group consisting of titanium, niobium, tantalum, zirconium, aluminum, and silicon (column 3, lines 11 – 12; column 4, lines 19 – 20), and wherein the electrode base member is further at least partially coated with an electrically conducting layer comprising at least one material selected from the group consisting of titanium nitride, niobium nitride, tantalum nitride, zirconium nitride, aluminum nitride, silicon nitride, vanadium nitride, iridium oxide, and an alloy of platinum and iridium, wherein the iridium portion of the alloy is ≥ 21 wt. % and the platinum portion of the alloy is \geq about 100 ppm (column 2, lines 20 – 21).

Art Unit: 3762

Regarding Claim 2, Bussard discloses an electrode base member is formed of at least one metal selected from the group consisting of titanium, tantalum, gold, carbon, platinum, iridium, platinum-iridium alloys, alloys based on cobalt and/or nickel, and stainless steel (column 3, lines 11 – 12; column 4, lines 19 – 20).

Regarding Claim 3, Bussard discloses a ceramic layer is arranged on an electrically conducting layer (column 4, lines 5 – 6 and 19 – 20).

Regarding Claim 4, Bussard discloses a ceramic layer is arranged adjacent an electrically conducting layer on an electrode base member (column 4, lines 5 – 6 and 19 – 20).

Regarding Claim 5, Jenkins discloses an electrically conducting layer is formed of titanium nitride (column 2, line 20).

Regarding Claim 6, Bussard discloses an electrically conducting layer of titanium nitride is at least partially covered with at least one oxidation protection layer on its side facing away from the electrode base member (column 4, lines 9 – 11).

Regarding Claim 7, Bussard discloses a ceramic layer is arranged on at least one oxidation protection layer (column 4, lines 12 – 13).

Regarding Claim 8, Bussard discloses a ceramic layer is arranged adjacent an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member (column 4, lines 5 – 6, 12 – 13, and 19 – 20).

Regarding Claim 9, Bussard discloses a ceramic layer is arranged adjacent at least one oxidation protection layer on an electrically conducting layer of titanium nitride (column 2, line 20; column 4, lines 5 – 6, 12 – 13, and 19 – 20).

Art Unit: 3762

Regarding Claim 10, Bussard discloses an oxidation protection layer is formed of at least one element selected from the group consisting of platinum, iridium, and gold (column 3, line 16).

Regarding Claim 14, Bussard discloses a ceramic layer has a surface closed in itself (Fig. 1).

Regarding Claim 15, Bussard discloses a ceramic layer has plurality of independent surfaces (Figs. 2 and 3; column 4, lines 52 – 54).

Regarding Claim 28, Bussard inherently discloses a form of a human implant (Abstract, line 1).

Regarding Claim 29, Bussard discloses a cardiac pacemaker electrode or a neuro-stimulation electrode (Abstract, line 1).

13. Claims 1 – 5, and 28 - 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Jenkins, U.S. Patent 6,606,523.

Regarding Claim 1, Jenkins discloses an electrically conducting electrode base member (column 4, lines 48 – 49) partially covered with an electrically insulating ceramic layer, wherein the ceramic layer is formed of an oxide and/or an oxynitride of at least one metal selected from the group consisting of titanium, niobium, tantalum, zirconium, aluminum, and silicon (column 5, lines 4 – 6), and wherein the electrode base member is further at least partially coated with an electrically conducting layer comprising at least one material selected from the group consisting of titanium nitride, niobium nitride, tantalum nitride, zirconium nitride, aluminum nitride, silicon nitride, vanadium nitride, iridium oxide, and an alloy of platinum and iridium, wherein the

Art Unit: 3762

iridium portion of the alloy is ≥ 21 wt. % and the platinum portion of the alloy is \geq about 100 ppm (column 5, lines 6 – 8).

Regarding Claim 2, Jenkins discloses an electrode base member is formed of at least one metal selected from the group consisting of titanium, tantalum, gold, carbon, platinum, iridium, platinum-iridium alloys, alloys based on cobalt and/or nickel, and stainless steel (column 5, lines 4 – 5).

Regarding Claim 3, Jenkins discloses a ceramic layer is arranged on an electrically conducting layer (column 5, lines 4 – 9).

Regarding Claim 4, Jenkins discloses a ceramic layer is arranged adjacent an electrically conducting layer on an electrode base member (column 5, lines 4 – 9).

Regarding Claim 5, Jenkins discloses an electrically conducting layer is formed of titanium nitride (column 5, lines 6 – 8).

Regarding Claim 28, Jenkins inherently discloses a form of a human implant (Fig. 1; column 1, lines 13 – 14).

Regarding Claim 29, Jenkins inherently discloses a human implant is a cardiac pacemaker electrode or a neuro-stimulation electrode (column 2, lines 6 – 9).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bussard as applied to claim 6 above, and in view of Bolz, U.S. Patent 5,609,611.

Regarding Claim 11, Bussard does not disclose an oxidation protection layer is formed of at least one compound selected from the group consisting of oxides, carbides, nitrides, and polymers, and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride, or at most increases the impedance to a value which is smaller than the impedance of the uncoated electrode base member. However, Bolz discloses an oxidation protection layer is formed of at least one compound selected from the group consisting of oxides, carbides, nitrides, and polymers, and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride, or at most increases the impedance to a value which is smaller than the impedance of the uncoated electrode base member (Fig. 6) for picking up heart signals for which the low-frequency range is particularly important, especially in the region where the signals are weak (column 8, lines 44 – 47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bussard to disclose an oxidation protection layer is formed of at least one compound selected from the group consisting of oxides, carbides, nitrides, and polymers, and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride, or at most increases the impedance to a value which is smaller than the impedance of the uncoated electrode base member, as taught by Bolz, for picking up heart signals for which the low-

Art Unit: 3762

frequency range is particularly important, especially in the region where the signals are weak (column 8, lines 44 – 47).

16. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bussard as applied to claims 1 and 6 above, and in view of Robblee, U.S. Patent 4,677,989.

Regarding Claim 12, Bussard does not disclose an oxidation protection layer has a thickness in a range of about 500 nm to about 5 μ m. However, Robblee discloses an oxidation protection layer has a thickness in a range of about 500 nm to about 5 μ m (column 4, lines 60 – 61) for providing a high-charge capacity and a corrosion-resistant interface to metallic electrodes used to inject charge into biological tissue with controlled electrical pulses (column 4, lines 28 – 31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bussard to disclose an oxidation protection layer has a thickness in a range of about 500 nm to about 5 μ m, as taught by Robblee, for providing a high-charge capacity and a corrosion-resistant interface to metallic electrodes used to inject charge into biological tissue with controlled electrical pulses (column 4, lines 28 – 31).

Regarding Claim 13, Bussard does not disclose a ceramic layer has a thickness in a range of about 1 nm to about 20 μ m. However, Robblee discloses a ceramic layer has a thickness in a range of about 1 nm to about 20 μ m (column 4, line 63) to ensure that dissolution will not result and the entire electrode will not disappear.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bussard to disclose a ceramic layer has a thickness

Art Unit: 3762


in a range of about 1 nm to about 20 μm , as taught by Robblee, to ensure that dissolution will not result and the entire electrode will not disappear.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


TLS
April 27, 2005
27 April 2005


GEORGE R. EVANISKO
PRIMARY EXAMINER

4/27/05